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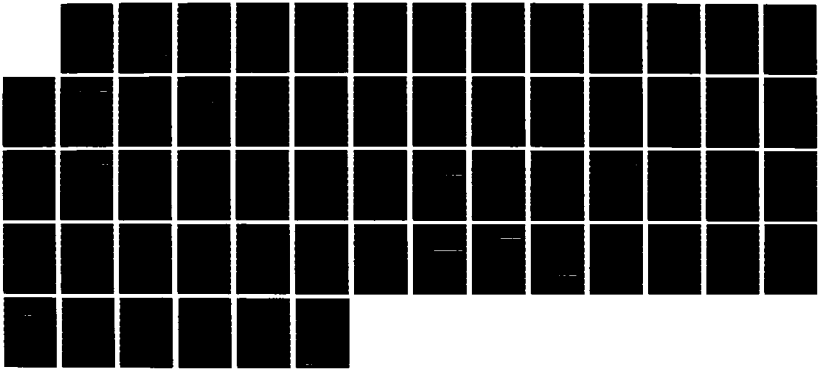

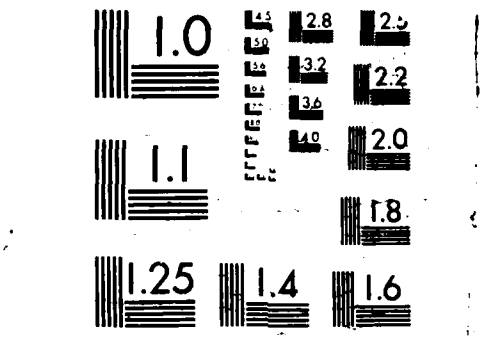
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United States General Accounting Office

GAO

Report to Congressional Requesters

October 1986

PESTICIDES

Need to Enhance FDA's Ability to Protect the Public From Illegal Residues

AD-A175 943

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United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-219498

October 27, 1986

The Honorable Dave Durenberger, Chairman
The Honorable Max Baucus, Ranking
Minority Member
Subcommittee on Toxic Substances
and Environmental Oversight
Committee on Environment and Public Works
United States Senate

As requested in your June 29, 1984, letter and subsequent discussions with your offices, we have reviewed the Food and Drug Administration's (FDA) activities to protect the public from exposure to illegal pesticide residues in the domestic food supply under the Federal Food, Drug, and Cosmetic Act. This report discusses the extent of FDA's coverage of the nation's domestic food supply and the concepts and factors FDA uses in selecting food samples for pesticide analysis; the capabilities of FDA to test for pesticide residues used or present in domestic food; and the ability of FDA to prevent domestic food found to contain illegal pesticide residues from reaching the market. This report is one of three companion reports. The other reports address the Environmental Protection Agency's (EPA) activities under the Federal Insecticide, Fungicide, and Rodenticide Act (GAO/RCED-86-125) and nonagricultural use of pesticides (GAO/RCED-86-97).

As arranged with your offices, unless you publicly release its contents earlier, we plan no distribution of this report until 30 days after the date of this letter. At that time, we will send copies to other appropriate congressional committees; the Commissioner, FDA; the Secretary, Department of Health and Human Services; the Administrator, EPA; the Director, Office of Management and Budget; and other interested parties upon request.

J. Dexter Peach
Assistant Comptroller General

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Executive Summary

Purpose

Pesticides are used extensively in American agriculture and residues of these pesticides on food need to be closely monitored to protect the public from harmful effects. The Food and Drug Administration (FDA) is responsible for monitoring the domestic food supply to identify food with illegal residues and to remove it from the market. Illegal pesticide residues are those that are not allowed to be present on food or are present in greater concentrations than those authorized by the Environmental Protection Agency. Such food is adulterated and cannot legally be marketed in interstate commerce.

The Chairman and Ranking Minority Member, Subcommittee on Toxic Substances and Environmental Oversight, Senate Committee on Environment and Public Works, asked GAO to examine FDA's (1) monitoring (sampling and testing) of the nation's domestic food supply for illegal pesticide residues and (2) efforts to prevent food containing illegal pesticide residues from reaching the market.

Background

The Federal Food, Drug, and Cosmetic Act gives FDA responsibility for prohibiting the interstate marketing of food containing illegal pesticide residues. Through its pesticide monitoring program, FDA collects samples of domestic food and tests each sample for certain pesticides primarily by using tests (known as multiresidue methods) capable of detecting large numbers of pesticides on a food sample. When FDA finds illegal residues in the food, the act gives FDA authority to prohibit it from being marketed through seizures or injunctions, and to seek criminal penalties against those who market adulterated foods.

Results in Brief

FDA has concluded that it cannot monitor all food that might contain illegal pesticide residues. Consequently, FDA has designed its monitoring program to act as a deterrent by selectively spot-checking a very small amount (probably less than 1 percent) of domestically produced food for illegal pesticide residues and to remove such food that it finds to contain such residues.

FDA's pesticide monitoring program as it is currently carried out has two major shortcomings:

- FDA does not regularly test food for a large number of pesticides that can be used or may be present in food. Included among these are a number

of pesticides that, according to FDA, require continuous or periodic monitoring because they are known as potential health hazards and are likely to be used.

- FDA does not (1) prevent the marketing of most of the food that it finds to contain illegal pesticide residues and (2) penalize growers who market food with illegal pesticide residues when FDA is unable to remove it from the market.

GAO is proposing a matter for congressional consideration and making a recommendation that should help to provide a more effective program to protect the public from adulterated food.

Principal Findings

FDA Samples a Very Small Portion of the Domestic Food Supply

FDA samples a very small, undefined portion of the domestic food supply.

- Between fiscal years 1979 and 1985, FDA Supply collected and analyzed 67,504 domestic food samples. FDA cannot estimate the percentage of the domestic food supply represented by its sampling but agrees that it is a very small percentage. Of the samples taken, 1,972, or 2.9 percent, were found to contain illegal residues. FDA officials said that since the samples they collect are not representative of the total food supply, the percentage of samples found to contain illegal pesticide residues do not represent the percentage of the total domestic food supply that might contain illegal pesticide residues.
- FDA believes that the criteria and approach used in designing and implementing the program provide the most appropriate coverage and are sufficient within available resources. These criteria include (1) sampling foods of dietary importance, (2) selectively sampling foods for pesticides posing a potential health risk, and (3) sampling foods where pesticide misuse is known or suspected. FDA district officials have considerable latitude in designing and implementing program coverage based on local pesticide problems within the overall general criteria. (See ch. 2.)

FDA Testing for Illegal Pesticide Residues Is Limited

FDA routinely tests each food sample for as many pesticides as possible by relying on multiresidue methods. FDA has developed five multiresidue methods that can each detect from 24 to 123 different pesticides but that cumulatively can detect less than half of the pesticide residues that

might appear in food. FDA has concluded that it should selectively test for other pesticides that cannot be detected by multiresidue methods if they pose a significant health hazard and are used.

Primarily because of time and resource constraints, FDA does not regularly test for pesticides that are not detected by multiresidue methods. Some of these pesticides, according to FDA, should be continuously or periodically tested because of their health hazard and likely usage, but FDA has not specifically defined how frequently this testing should take place. GAO identified 33 such pesticides that are not detected by any of the five multiresidue methods. Between fiscal years 1979 and 1985, FDA (1) did not test any domestic food samples for 5 of the 33 pesticides and (2) tested 17 of the remaining pesticides from 6 to 269 times during this 7-year period. (See ch. 3.)

Penalties Are Not Being Assessed for Marketing Adulterated Foods

For FDA to effectively enforce pesticide residue limits, it must be able to remove domestic food containing illegal pesticide residues and penalize growers who ship such food and do not remove it from the marketplace. In 107 of 179 pesticide violations GAO reviewed, FDA did not remove any of the food and in no cases did FDA penalize growers who shipped the food. FDA's position is that it does not remove more food or penalize growers because existing legislative authority is not well suited for pursuing pesticide violations on domestic food. This is because FDA (1) cannot detain domestic food containing illegal pesticide residues while it seeks court action to remove it from the market and (2) must rely on criminal penalties that require extensive evidence gathering and are costly to prosecute because FDA does not have the authority to impose civil penalties on growers who market adulterated food. GAO has previously proposed that FDA be granted detention authority and continues to support this proposal. (See ch. 4.)

Matters for Congressional Consideration

In view of the difficulties that FDA faces in trying to use existing authorities against domestic foods found to contain illegal pesticide residues and the need to provide a strong deterrent against such shipments, the Congress may wish to give FDA legislative authority to assess civil penalties against growers of such food when it is not removed from the marketplace (see p. 58).

Recommendation

GAO recommends that the Secretary of Health and Human Services direct the FDA Commissioner to establish specific criteria for the level of

testing that is required for continuous and periodic monitoring and require FDA laboratories to test in accordance with such criteria (see p. 44).

Agency Comments

The views of responsible officials were obtained during GAO's review and are incorporated into this report as appropriate. As requested, GAO did not obtain official agency comments on a draft of this report.

Contents

Abbreviations

EDB	ethylene dibromide
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FD&C	Federal Food, Drug, and Cosmetic Act
GAO	General Accounting Office
HRD	Human Resources Division, GAO
RCED	Resources, Community, and Economic Development Division, GAO

Introduction

Pesticides are chemicals that are used extensively in American agricultural production to destroy or control weeds, insects, fungi, and other pests. According to the Environmental Protection Agency's (EPA) most current estimates, American agriculture's use of pesticides increased from 320 million pounds in 1964 to about 733 million pounds in 1983. Although pesticides contribute significantly to agricultural productivity, exposure to pesticides can adversely affect human health. Some pesticides exhibit evidence of causing chronic health effects such as cancer or birth defects and some persist in the environment over long periods of time and accumulate in the tissues of plants, animals, and people. Many pesticides used in agriculture remain on the food and can be ingested along with the food.

Because of the potential adverse health and environmental effects associated with pesticides, federal laws have been enacted to regulate the use of pesticides and the amount of the residue of each pesticide that is allowed to be present in food. Pesticide use is governed by the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), which assigns responsibility for federal registration and use of pesticides to EPA. The Federal Food, Drug, and Cosmetic (FD&C) Act, as amended (21 U.S.C. 301 et seq.), governs which pesticides are allowed to remain as residues on individual food commodities, and in what amounts, by assigning responsibility to

- EPA for determining which individual pesticide residues and in what amount (referred to as pesticide tolerances[1]) will be allowed to be present in specific foods without causing the food to be considered legally adulterated, and
- the Food and Drug Administration (FDA) under the Department of Health and Human Services to enforce the pesticide residue tolerances established by EPA for all food products except for meat, poultry, and eggs.

The United States Department of Agriculture monitors meat, poultry, and eggs for illegal pesticide residues under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

[1]A pesticide residue tolerance represents an amount of the pesticide residue that EPA has concluded can be consumed without presenting an unreasonable health risk and that should not be exceeded on the crop(s) for which it is registered when it is used as specified in its federal registration.

This report discusses FDA's efforts to enforce the FD&C Act's prohibition against the marketing of food with illegal pesticide residues. EPA's responsibilities are discussed in a companion report entitled Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks (GAO/RCED-86-125, dated April 18, 1986). We did not review the Department of Agriculture's activities.

FDA's Role in Monitoring the Food Supply for Illegal Pesticide Residues

The FD&C Act prohibits the interstate sale of adulterated (unsafe) food, drugs, cosmetics, medical devices, and other related products; makes FDA responsible for enforcing their prohibition; and authorizes FDA to take certain action against adulterated products and growers or producers responsible for them. Section 402 of the act specifies that food is adulterated if, among other things, it contains either (1) a residue of any pesticide that is not subject to an EPA-approved tolerance (i.e., approved by EPA for use on or in food) or (2) a pesticide residue in an amount greater than the amount allowed on a food commodity by EPA under sections 408 and 409 of the act.[2]

Although FDA is responsible for assuring that the public's food does not contain residue levels above those specified by EPA, FDA has concluded that it is "impossible to monitor routinely for all possible chemical residues and to detect and remove each and every shipment of food and feed that may contain illegal residues." A 1979 internal FDA evaluation of the pesticide monitoring program cited the following factors which led to this conclusion:

- The large number of pesticide chemicals that can legally be applied to crops as well as an unpredictable number of pesticides that can contaminate food because of misuse (i.e., pesticides are not applied in accordance with federal regulations) or persistance in the environment.
- Seasonal and geographical pesticide use patterns that can complicate FDA's ability to predict which residues may be potentially present in a given food shipment.
- The sheer volume of food that can potentially be contaminated by multiple residues or may not be contaminated at all.

Consequently, FDA has designed a program that selectively covers certain types of food and pesticides and is directed at deterring the marketing of food containing illegal pesticide residues. FDA samples a

[2]The act also defines an adulterated product as one that is defective, unsafe, filthy, or not produced under sanitary conditions.

relatively small portion of the food and animal feed that is domestically produced and tests the samples for the presence of selected pesticide residues. The purpose of the analysis is to determine if the food from which the sample is taken contains pesticide residues that are either not allowed on the food or present in an amount that is greater than the amount allowed by EPA.

When FDA's tests confirm that the sampled food contains illegal pesticide residues, FDA is responsible for preventing it from being marketed through interstate commerce. The act authorizes FDA to (1) seize food containing illegal pesticide residues,(2) seek injunctions against future shipments of food containing illegal pesticide residues, and (3) seek criminal penalties against those who intentionally market food containing illegal pesticide residues. In addition, the act also authorizes FDA to issue written warnings which FDA uses to require growers or producers to initiate corrective actions to prevent violations from recurring.

FDA's sampling and testing of food for pesticide residues is primarily directed by the Center for Food Safety and Applied Nutrition and the Associate Commissioner for Regulatory Affairs and carried out in FDA's 22 district offices and 16 laboratories capable of analyzing samples for pesticide residues. Most employees involved with pesticide monitoring are located in the district offices and laboratories; they include chemists and laboratory support staff who test food samples for residues, as well as investigators who collect food samples and gather information about pesticides being used at the local level. The remaining staff members involved with the program are in headquarters and include program personnel who review field data, evaluate compliance problems, and plan programs as well as chemists and others who conduct research to expand the capabilities of current testing methods.

FDA's resources—people and money—devoted to the program are based on the priority FDA gives to pesticides relative to its other legislatively mandated responsibilities such as drugs, animal feeds, medical devices, and other aspects of food and product safety. During fiscal year 1985, FDA's total budget was about $397.5 million and 7,000 staff years. FDA allocated about $13.7 million (3.4 percent) and 309 staff years (4.4 percent) of the budget to monitoring both domestic and imported foods, animal feeds, processed foods, cosmetics, and other products for pesticides. Table 1.1 shows the resource levels that FDA estimates were devoted to pesticide monitoring between fiscal years 1979 and 1985.

Table 1.1: Resource Levels for Fiscal Years 1979-85

Fiscal year	Resource levels	
	Dollars (Millions)	Staff years
1979	$11.7	325
1980	12.7	344
1981	12.5	330
1982	12.3	315
1983	12.4	309
1984	13.0	309
1985	13.7	309

States' Role in Monitoring the Food Supply for Illegal Pesticide Residues

Although FDA regulates food moving through interstate commerce, it is not alone in attempting to protect the public from illegal pesticide residues. Many states have laws similar to the FD&C Act which require state monitoring programs to detect illegal residues on food that is produced and sold intrastate. According to the most recent information provided by FDA, 38 states have programs to collect and analyze samples for pesticides. FDA estimates that states annually collect and analyze about 50,000 food samples for pesticide residues. The extent of coverage varies among the states.

Objectives, Scope, and Methodology

In a June 29, 1984, letter and subsequent meetings, the Chairman and the Ranking Minority Member of the Senate Subcommittee on Toxic Substances and Environmental Oversight, Senate Committee on Environment and Public Works, asked us to provide information on federal efforts to regulate pesticides to protect the public. As part of this request we were asked to provide information on two questions concerning FDA's monitoring and enforcement of pesticide residues in the domestic food supply.

1. How does FDA monitor the public's food supply for pesticide residues to ensure that the public is being protected from unsafe levels?

2. What are FDA's enforcement strategies and are they preventing food with illegal levels of pesticide residues from reaching the marketplace?

As part of this request we have also issued two other reports addressing EPA's activities under the Federal Insecticide, Fungicide, and Rodenticide

Act. These are (1) Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks (GAO/RCED-86-125) and (2) Nonagricultural Pesticides: Risks and Regulation (GAO/RCED-86-97).

Our review was performed at FDA headquarters in Washington, D.C., and Rockville, Maryland. We also performed work at the Atlanta, Chicago, Dallas, Detroit, Los Angeles, Minneapolis, Orlando, San Francisco, and Seattle district offices; and at the Atlanta, Dallas, Detroit, Los Angeles, Minneapolis, San Francisco, and Seattle laboratories. These locations were selected because they represent about 59 percent of the domestic food sampled and analyzed nationally by FDA and about 66 percent of all domestic pesticide violations.

We reviewed agency policies and procedures concerning FDA's pesticide monitoring program, as well as appropriate laws, regulations, and manuals, to determine FDA's authorities and procedures for implementing the pesticide monitoring program and enforcement actions.

To determine how FDA designs its sampling and testing coverage, we reviewed (1) a 1979 internal FDA evaluation of its monitoring programs for pesticide and industrial chemical residues in food which evaluated the pesticide monitoring program and made recommendations to improve pesticide monitoring and enforcement activities, (2) progress reports and other reports, studies, evaluations, policy notes, and annual program guidance, and (3) program budget documents. We also reviewed information on samples FDA took between fiscal years 1979 and 1985 to identify the (1) types of food commodities that FDA sampled and analyzed and (2) numbers of samples FDA found to contain illegal pesticide residues.

To determine the extent of FDA's testing coverage of pesticide residues when enforcing tolerances, we reviewed FDA's Pesticide Analytical Manual and obtained information on pesticides covered and not covered by FDA's multiresidue methods (methods which test for a number of pesticides having similar physical or chemical characteristics). We compared the pesticides that cannot be detected by any of FDA's multiresidue methods against the most recent agricultural usage estimates provided by EPA and the potential health effect data provided by FDA. We also obtained information from FDA on the numbers of domestic samples collected and analyzed for pesticide residues for fiscal years 1979-85 to determine the extent to which FDA uses available tests to detect pesticides not covered by its most commonly used multiresidue methods.

As part of our assessment concerning FDA's testing coverage, we also selected seven commonly eaten commodities (apples, cabbage, corn, grapefruit, grapes, oranges, and lettuce) in selected FDA laboratories where the commodity is one of the major crops grown in the district serviced by the laboratory. We used these seven commodities to determine the extent to which pesticides that FDA has identified as posing a moderate to high health hazard are being tested through methods other than FDA's multiresidue methods. Table 1.2 shows the selected crops and the corresponding FDA laboratories.

Table 1.2: Selected Crops by FDA Laboratory

Selected crops	FDA laboratory
Oranges	Atlanta
Grapefruit	Atlanta
Apples	Seattle and Detroit
Lettuce	Dallas and Los Angeles
Cabbage	Dallas
Corn	Minneapolis
Grapes	Los Angeles and San Francisco

For each commodity selected, we obtained information on pesticides registered for use by the state on the commodity and, to the extent possible, the most current available data on the number of pounds of pesticides either sold or recommended for use on the crop in the state. With the assistance of district laboratory officials, we identified the extent to which these pesticides were tested in fiscal year 1984 on the selected crops. Fiscal year 1984 data were used because they represented the most complete information available at the time we conducted our review. We also obtained information from FDA to determine if other methods were used to test for pesticides that cannot be detected by FDA's multiresidue methods.

To assess FDA enforcement actions, we obtained information on 222 pesticide-related violations between October 1, 1983, and June 30, 1985, at the districts we visited. For each violation we attempted to (1) identify the enforcement actions FDA used and (2) determine the amount of adulterated product identified, the amount seized or destroyed, and the time required to implement the specific action. However, because FDA files did not have complete information, we were unable to determine, for 45 violations, the amount of adulterated food that was prevented from reaching the market.

We also visited state officials responsible for monitoring and enforcing pesticide residues on food in Arizona, California, Florida, Illinois, Michigan, Minnesota, Oregon, Texas, and Washington to obtain information about agricultural production, pesticide usage, and enforcement actions that states take to remove food from the market when FDA finds a pesticide violation. These states are among the largest agricultural producers within the geographic responsibility of the FDA district and laboratory offices selected. We also attempted to obtain information about local pesticide usage from EPA officials and other local officials. We did not review state programs to determine if they provided adequate sampling, testing, and enforcement for illegal pesticide residues.

Our work was performed between September 1984 and January 1986, with additional information obtained through September 1986, in accordance with generally accepted government auditing standards. The views of directly responsible officials were sought during the course of our work and are incorporated in the report where appropriate. As requested, we did not obtain official comments on a draft of this report.

Chapter 2

FDA Samples a Very Small Amount of Domestically Produced Food

To deter the interstate marketing of food containing illegal pesticide residues, FDA must be able to determine if the food does, in fact, contain illegal pesticide residues. To make this determination, FDA must collect samples of food and test the food for illegal pesticide residues.

Because of the enormous amount of food that is domestically produced and marketed interstate and the resources required to analyze foods for pesticide residues, FDA's pesticide monitoring program is directed at spot-checking food for illegal pesticide residues by sampling a relatively small (probably less than 1 percent) but undefined portion of domestic food production. In selecting food samples for laboratory analysis FDA emphasizes sampling (1) foods that are of dietary importance, (2) foods that are known or likely to be treated with pesticides posing the most significant potential health risks, and (3) growers and crops whose pesticide problems are known, suspected, or most likely to occur. Using these general factors, FDA district officials decide which specific coverage is most appropriate on the basis of local agricultural production, potential problem areas, and other considerations.

FDA has taken two initiatives to increase its sampling of the domestic food supply. By using modified sample collection and processing procedures, several FDA districts have been able to achieve some significant increases in the number of domestic samples they are able to collect and analyze without any increase in resources. Also, some FDA districts are coordinating with states that have similar programs. However, FDA's ability to increase coverage through coordinating with states is limited: some states do not have programs designed to routinely monitor food for illegal pesticide residues and for some states that do, coordination arrangements could not be worked out.

Between fiscal years 1979 and 1985, FDA collected and analyzed 67,504 domestic food samples. The percentage of domestic food samples found to contain illegal pesticide residues ranged from a high of 4.2 percent in fiscal year 1980 to a low of 1.8 percent in 1984 and averaged 2.9 percent between fiscal years 1979 and 1985. FDA officials maintain that the level of domestic food samples collected is sufficient relative to the resources available for the program and because a relatively small percentage of samples is found to contain illegal pesticide residues. These officials stated that even if additional resources were available, they would not be used to collect more food samples but would be used to increase the number of pesticides that are tested for.

FDA Samples a Small but Undefined Portion of Domestic Food for Illegal Residues

Program officials cannot define the exact extent of coverage provided by the Pesticide Monitoring Program because they are unable to adequately define the magnitude and composition of the domestic food supply. Also, FDA does not accumulate information on the amount of food that is represented by all the food samples it collects and analyzes for pesticide residues. Consequently, an accurate estimate cannot be made about the percentage of domestically produced food represented by the number of samples collected and analyzed by FDA. From available information it appears that only a very small amount, probably less than 1 percent, of the nation's domestic food production is represented by FDA's domestic sampling.

The amount of domestic food production is enormous and both production and distribution are very decentralized. FDA estimates annual food consumption in the United States to be in excess of 250 billion pounds. Further, the food consumed is comprised of thousands of different crops that are produced on more than 2 million farms. These crops may then either be (1) sold directly to consumers via roadside or open market stands, (2) trucked directly from the farm to food stores, (3) gathered at warehouse or other distribution centers for subsequent sale to retail food stores, or (4) sold to food processors who convert the raw agricultural products into processed food products which are then sold to consumers.

Because it is not possible to reliably estimate what portion of the domestic food supply FDA samples, we developed an illustration to indicate the portion of domestic food production represented by FDA's sampling. As noted earlier, FDA estimates that in excess of 250 billion pounds of food is marketed annually. During fiscal year 1985 FDA collected and analyzed 11,850 domestic food samples. Assuming that each of these samples represents a food lot weighing 40,000 pounds, then the 250 billion pounds of food consumed annually would consist of about 6.25 million food lots. Assuming that each of the 11,850 domestic samples represents different lots, then FDA samples represent less than two-tenths of 1 percent of domestic food production.

On the basis of this illustration, it is evident that even if FDA were to increase its sampling by several times (i.e., tripling or quadrupling the number of samples), it would still be sampling only a very small portion of domestic food production. Yet to do so would probably require tripling or quadrupling the current program resources of about $13.9 million and 309 staff years.

FDA has recognized that its pesticide monitoring program covers only a relatively small but undefined portion of the food supply and that it can only selectively monitor a small amount of the food supply for illegal pesticide residues. Consequently, FDA has established the following program objectives:

- Selectively cover pesticides that pose a significant health risk and are likely to occur in food.
- Routinely cover foods of dietary importance that have the potential for containing residues of concern.
- Selectively cover residue and commodity combinations for which actual pesticide usage is determined or highly suspected and may pose a significant health risk.
- Periodically cover other pesticides that may occur in the food supply.
- Cover emerging and suspected residue problems.

FDA Sampling Is Judgmental and Decentralized

The extent to which individual food commodities and the products of individual growers are sampled is the result of individual sampling decisions made by FDA inspectors and district officials. Such decisions are based on the sampling priorities established by FDA headquarters as well as districts' knowledge of local agricultural conditions, practices, and problems.

FDA Headquarters Role in Food Sampling

Prior to 1979, FDA headquarters centrally planned the pesticide monitoring program. However, a 1979 internal evaluation by FDA was critical of this approach because it did not account for the wide variety of pesticide situations that may be present at the local level. Consequently, FDA revised its approach to reduce headquarters involvement in designing and implementing the program.

FDA headquarters annually provides guidance and specifies the pesticide monitoring resources and the minimum number of samples to be collected and analyzed by each district office. FDA headquarters also specifies coverage of certain crops and/or pesticides that each district office should incorporate into its local program through the core and special survey elements in its annual program guidance.

Under the core element, each district office is required to devote a portion of its program resources to collecting and analyzing fish, eggs, milk, and dairy products for residues because they most likely contain fat

soluble pesticides as well as pesticides that can remain in the environment.

FDA generally uses the special survey element to cover pesticides that pose a potential health hazard but that are not detected by the testing methods generally used for pesticide monitoring (see ch. 3). Pesticides are also included in a special survey when EPA requests FDA to collect information on the level of specific pesticide residues appearing in food. For example, since fiscal year 1983, FDA headquarters has directed its district offices to participate in a special survey of ethylene dibromide (EDB) in grains and fruits. This survey was done because EPA requested information on the extent to which EDB residues were appearing in certain crops because of concerns that the pesticide could cause cancer. FDA program officials said that very few samples were found to contain residue levels of concern.

FDA's annual program guidance directs its districts to analyze and collect samples under both the core and special survey elements. For example, in fiscal year 1985 FDA directed each district to collect

- at least 12 shell egg samples,
- at least 24 milk and/or cheese samples at bottling plants or cheese plants with a minimum of 4 samples per state, and
- a total of 10 samples of fruits or vegetables known to have been treated with ethylenebisdithiocarbamate fungicides.

Also, FDA directed that 11 districts each collect and analyze at least 10 grain samples for pesticide fumigants. Further, districts were instructed to analyze some samples for pesticides such as malathion, aldicarb, carbofuran, synthetic pyrethroids, benomyl, and thiophanate-methyl.

FDA District Offices Have Considerable Latitude in Determining Sampling Coverage

District offices have considerable latitude in determining what coverage will be provided over and above the core or special survey elements required by FDA headquarters. District offices rely on pesticide coordination teams, consisting of an investigator, a chemist, and a compliance officer, to design and implement coverage based on local conditions. According to district officials, the following factors are considered in designing district pesticide monitoring programs: crops of local dietary importance, local pest problems, local pesticide usage, extent of past pesticide misuse, and local harvesting seasons. Also, indications of potential problems are received from states, the U.S. Department of Agriculture, EPA, consumers, or other sources. However, the extent to

which local officials consider any or all of these factors in designing their coverage and in selecting individual samples cannot be determined because the districts do not prepare formal sampling plans or maintain documentation to support their individual decisions on why specific samples are collected and analyzed.

Each district develops coverage based on its unique needs and local problems. The following examples serve to illustrate how local coverage is determined in different districts:

- According to Chicago district officials, most of their sampling is directed toward fish. The district has concentrated on sampling fish in Lake Michigan because of known contamination problems with some potentially dangerous pesticides that persist in the environment for long periods of time.
- Dallas primarily concentrates its sampling coverage on major agricultural areas having a history of pesticide misuse. For example, the district concentrates its efforts in the Rio Grande Valley, a major agricultural area in southern Texas having a history of high pesticide misuse. The district does not extensively cover Oklahoma and New Mexico because their agricultural production areas are much smaller than those in Texas and their climates inhibit the growth of pests that attack commodities.
- Detroit considers past violations, types of pesticides being found, extent of crop production, and concerns about particular pesticides in designing its coverage. District officials said that leafy vegetables such as lettuce and spinach and root crops such as potatoes and carrots are frequently sampled because pesticides tend to get into the leaves and are more difficult to wash out.
- Los Angeles officials said that they concentrate coverage in California primarily on fresh fruits and vegetables. In designing coverage, officials said that they consider such factors as the type of crops being grown, the time of year when crops are grown, pesticide usage data, past pesticide violations, time which has elapsed since prior sampling was conducted, and known or suspected problems. Los Angeles district officials said that they must cover all major growing regions in southern California because it is one of the largest agricultural producing areas in the United States. Because of the large growing area, the district concentrates on collecting samples from packing sheds instead of the farmers' fields. The district does less sampling in Arizona because its agricultural production areas are much smaller and fewer crops are grown.

District officials said that FDA's conceptual approach provides them with the flexibility to react to known or suspected problems and allows them to obtain the most appropriate and the broadest coverage possible within existing resources.

FDA Initiatives to Increase Sampling and Coverage of Domestic Food

Although resources devoted to the pesticide monitoring program have declined over the past several years, two initiatives have allowed FDA to enhance the numbers of samples that it can collect and analyze as well as their coverage of commodities. These initiatives are (1) modifying sample collection and processing procedures and (2) coordinating with states having similar programs.

Modified Sample Collection and Processing Procedures Have Increased Productivity

Modifications to FDA's prescribed sample collection and processing procedures have enabled several FDA districts to significantly increase the number of food samples they are able to collect and analyze without any significant increase in allocated resources. FDA headquarters has encouraged districts to use modified procedures where appropriate.

FDA's sample collection and processing instructions prescribe very precise and time-consuming procedures for collecting a food sample and packaging it for shipment to the laboratory for analysis. In addition, the procedures instruct FDA officials to prepare all the reports and documents that would be required to support FDA regulatory action if the sample is subsequently found to contain illegal pesticide residues.

FDA's Los Angeles District Office has developed alternative approaches to collecting and preparing reports for individual food samples. According to district officials, instead of using the prescribed procedures for collecting, packaging and shipping samples, the district ships one whole crate of a commodity to the laboratory. Also, rather than prepare all the reports and documents on all samples collected, the district records the necessary data in a computer and prepares the documents only in those cases where FDA is seeking a regulatory action. The Los Angeles district office found that these modifications significantly reduced the time and effort involved in collecting and processing food samples and allowed them to significantly increase the amount of sampling they could accomplish with existing resources. For instance, in fiscal year 1984 Los Angeles was able to dramatically increase the number of samples it was able to collect and analyze—1,336—over the number it was expected to be able to handle with its allocated resources—599.

FDA headquarters has encouraged other FDA districts to modify their procedures. However, FDA headquarters has left the choice of modifying procedures to the discretion of district officials.

In 1984, three of the other eight FDA district offices we visited—San Francisco, Seattle, and Orlando—adopted modified sample collection and reporting procedures and were able to significantly increase their sampling, as indicated in the following examples:

- In fiscal year 1984, the San Francisco and Seattle districts adopted essentially the same techniques as the Los Angeles district for collecting domestic food samples. As a result, both districts significantly increased the number of samples they collected and analyzed within available resources. For example, San Francisco increased the number of samples collected from 958 in fiscal year 1983 to 2,125 in fiscal year 1984. During the same period, Seattle increased the number of samples collected from 759 to 1,345.
- At the beginning of fiscal year 1984, the Orlando district changed its approach to collecting samples in order to increase the number of samples tested. Orlando district inspectors were able to speed up the sampling process by using abbreviated collection reports and modified sampling collection procedures. Orlando officials said that the modified procedures have increased the district's sampling by 50 percent.

A fourth district, Dallas, indicated that it intended to use the modified procedures. Officials in other districts said that they did not believe the modified procedures were appropriate for use in their districts.

Coordinating With State Agencies Has Enhanced FDA Coverage

FDA has enhanced its ability to cover more foods by coordinating with states having similar programs. Each of the districts we visited coordinated with states within its geographic jurisdiction by sharing information about program coverage and results. Two districts took additional steps in designing their program coverage.

- The Seattle district and Oregon split crop coverage to monitor commodities for illegal pesticide residues. FDA agreed to cover certain crops and Oregon others. FDA officials said that this approach improved their ability to sample more food without additional resources.
- The Dallas district and New Mexico began a project in fiscal year 1985 whereby New Mexico agreed to collect and analyze at least 13 samples of 7 food products for illegal pesticide residues. Officials from Dallas

and New Mexico stated that such a project would allow them to expand coverage without increasing resources.

While close coordination may be possible in some districts, it may not be feasible in others because states may not have programs designed to test food for illegal pesticide residues. Data provided by FDA show that only 38 states had programs to monitor for illegal pesticide residues in food. According to FDA program officials, their ability to closely coordinate with states depends on state officials' attitudes concerning the importance of monitoring for illegal residues and the states' ability to devote the necessary resources to develop comprehensive programs for monitoring food for illegal pesticide residues.

FDA Results Indicate That About 3 Percent of Domestic Food Samples Contain Illegal Pesticide Residues

FDA program results indicate that approximately 3 percent of all domestic food samples collected and analyzed contained illegal residues. Data indicate that between fiscal years 1979 and 1985, FDA collected 67,504 domestic food samples and found that 1,972 (2.9 percent) contained illegal residues. The percent of domestic samples containing illegal residues varied from a low of 1.8 percent in fiscal year 1984 to a high of 4.2 percent in fiscal year 1980. Table 2.1 shows the number of domestic samples collected and the number found to contain illegal residues between fiscal years 1979 and 1985.

Table 2.1: Domestic Samples Collected and Found to Contain Illegal Residues Between Fiscal Years 1979 and 1985

Year	Number of samples collected and analyzed	Number found to contain illegal residues	Percent of samples containing illegal residues
1979	6,758	265	3.9
1980	7,850	333	4.2
1981	7,095	202	2.8
1982	7,013	234	3.3
1983	8,513	310	3.6
1984	18,425	328	1.8
1985	11,850	300	2.5
Total	**67,504**	**1,972**	**2.9**

According to FDA program officials, results indicate that very little of the food sampled and tested contains illegal pesticide residues. However, the officials said that these results are representative only of the foods sampled and pesticides tested by FDA and should not be considered representative of the extent to which illegal pesticide residues are present in

domestically produced food. Besides sampling a very small portion of the food supply, FDA does not analyze the samples it collects for every potential pesticide residue (see ch. 3).

According to program officials, the dramatic increase in the number of samples collected and analyzed in fiscal years 1984 and 1985 was primarily attributable to a diversion of resources from other priorities to carry out large special surveys on the pesticides EDB and carbon tetrachloride. Another factor contributing to FDA's ability to perform increased sampling is the districts' use of modified sampling and collection procedures. According to these officials, the number of samples that will actually be collected and analyzed is difficult to predict from year-to-year because of factors such as what is being found, local problems, and competing priorities. FDA plans to take 10,000 food samples in fiscal year 1986; about 5,600 samples are estimated to be for domestic food while the remainder will be for imported food. According to FDA officials, the 10,000 food samples planned for fiscal year 1986 is the same number as planned for in prior years.

While less than 3 percent of the domestic food sampled and analyzed contains illegal residues, some commodities have a greater likelihood of containing illegal residues than others. Dairy products had the lowest percentage of samples (0.4 percent) containing illegal pesticide residues, while fish had the highest percentage (5.2 percent). Table 2.2 shows the percentage of eight different commodity groups sampled that contained illegal pesticide residues.

Table 2.2: Domestic Samples Collected and Analyzed by Food Groups Between Fiscal Years 1979 and 1985

Commodities	Number of samples	Percent of total	Number found to contain illegal residues	Percent of samples containing illegal residues
Leafy and other vegetables	13,963	20.7	515	3.7
Fruits and fruit products	10,197	15.1	75	0.7
Fruits used as vegetables[a]	4,161	6.2	84	2.0
Beans-corn-peas	3,085	4.6	36	1.2
Fish	4,505	6.7	233	5.2
Eggs	2,951	4.4	79	2.7
Grains[b]	10,453	15.5	348	3.3
Dairy products	5,934	8.8	21	0.4
Others[c]	12,255	18.2	581	4.7
Total	**67,504**	**100.2[d]**	**1,972**	**2.9**

[a]Includes tomatoes, peppers, pimentos, and eggplants

[b]Includes grains, cereals, bakery products, and noodle products

[c]Includes all other foods categories such as soft drinks, tea, snack items, and animal feeds

[d]Does not equal 100 percent due to rounding

FDA program officials said that they believe the current number of domestic samples that are collected and analyzed is sufficient relative to resources available for the program and the relatively low percentage of samples found to contain illegal pesticide residues. According to these officials, even if additional resources were available for the program, they would not be used to increase the number of domestic samples that are collected but would be used to increase the numbers of pesticides that are tested for.

Conclusions

Given the volume of domestically produced food that is annually consumed, FDA is faced with an enormous task in determining if food contains illegal pesticide residues. FDA has concluded that it cannot sample a very large portion of all the food that is produced annually to test it for illegal pesticide residues. Consequently, FDA spot-checks a very small amount of this food. FDA headquarters provides general guidance for sampling and also specifies certain minimum sampling that districts must accomplish. However, the actual selection of food samples depends on the knowledge and judgments of individuals located throughout the United States. FDA believes that by concentrating on foods of dietary importance, pesticides of concern, and known or suspected problem

areas, as well as by relying on the individual judgments of local FDA officials, it is able to provide the broadest and most appropriate coverage of the domestic food supply.

FDA's initiatives to increase sampling thru modified sample collection and processing procedures and coordinated sampling plans with state governments are steps in the right direction to obtain more and better coverage of the nation's food supply. We encourage FDA to continue these initiatives, especially with respect to coordinated sampling efforts with the states.

Limits of FDA's Testing for Illegal Pesticide Residues in Food

FDA lists 496 pesticides that either are registered for use on food or could possibly show up as residues in food. Literally thousands of commodity and residue combinations exist, according to FDA program officials.

FDA does not analyze each domestic food sample for all possible residues because of limitations with existing testing methods as well as time and resource constraints. Because multiresidue test methods are most cost-effective, FDA normally analyzes domestic food using one of five such methods it has developed. The number of pesticides detected by each method varies from 24 to 123 (i.e., the maximum number of pesticides that might be tested for using a multiresidue method is 123), but it is unlikely that FDA will test a food sample for all pesticides the method is capable of identifying. In combination the five are known to detect 203 (40.9 percent) of the 496 pesticides. This means that other single-residue or less comprehensive multiresidue methods would have to be used to test for the 293 pesticides that are not known to be detected through any of FDA's five multiresidue methods.

FDA initiated actions, beginning in 1979, to improve its testing coverage. These actions involved (1) establishing the surveillance index program that classifies pesticides which need to be tested according to their potential health hazards (the hazards are based on the pesticide's toxicity, chemical properties, use, and potential for dietary exposure) and (2) testing for those pesticides posing the most significant health hazards. Our review of these actions indicates that:

- Surveillance index classifications have been completed for 186 pesticides and are planned for 135 additional pesticides with permanent food tolerances established by EPA. FDA does not plan to develop surveillance index classifications for the other pesticides that might possibly show up as residues in food if they are either exempt from the requirement for tolerances or are not registered for use on food. However, FDA officials said that they will develop surveillance index classifications for individual pesticides in these two categories if they learn of significant toxicity or residue problems related to a pesticide. Further, FDA's surveillance index classifications may have to be reevaluated depending on the result of EPA's pesticide reregistration efforts, which may take several decades.[1]
- FDA is not regularly testing for a number of pesticides that are not detected by multiresidue methods and that, according to FDA, require

[1]The status of EPA's reregistration efforts is discussed in GAO's report entitled Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks (GAO/RCED-86-125, Apr. 18, 1986), ch. 2.

continuous or periodic testing because of their potential health hazard and likely usage. We identified 33 such pesticides. Between fiscal years 1979 and 1985, FDA provided data showing that 5 of the 33 pesticides were not tested at all; and 17 of the remaining pesticides were tested from 6 to 269 times.

- FDA laboratories we visited did not test for pesticides on selected foods (apples, cabbage, corn, grapefruit, grapes, lettuce, and oranges) during fiscal year 1984 if they were not detected by the multiresidue method used by the laboratory. These tests were not performed even though (1) it was likely the pesticides were used on these foods and (2) FDA's surveillance index program requires continuous or periodic monitoring of these pesticides.

Potential for Pesticide Residues

Illegal pesticide residues are those that are either not allowed to be present on a specific crop or are present in an amount that is greater than the amount allowed by EPA's established tolerance. The exact number of pesticides that might show up as residues in food is not known, but FDA has listed 496 pesticides with residue potential. These include about 400 pesticides that are registered by EPA for food uses and others that, although not registered for use on food, have on occasion been found by FDA to be present in food. According to FDA, permanent tolerances are in force for 316 pesticides that are either (1) currently registered for use on food or (2) their registered food uses have been either suspended or cancelled but can show up in food because of their persistence in the environment.

Pesticides on the list of 496 without permanent tolerances include pesticides that are (1) registered for food uses but have been exempted by EPA from the requirement for a tolerance,[2] (2) temporarily authorized for use in food on an emergency or experimental basis, and (3) not registered for use on food.

Overview of Testing Methods and Their Inherent Limitations

To enforce tolerances FDA must have testing methods that are capable of detecting and identifying pesticide residues in food. Two general categories of testing methods exist—single-residue methods and multiresidue methods. Because multiresidue methods are more cost-effective and allow FDA to identify many pesticides that may be present on food, FDA relies on five multiresidue methods it has developed. Cumulatively,

[2]Under section 408 of the FD&C Act, EPA can exempt a pesticide from a tolerance requirement when, in its opinion, the pesticide does not pose a health risk to the public.

these five methods detect fewer than one-half of the pesticides that are used on or can be present in food because of misuse or contamination. Because of time and resources, as well as scientific limitations with testing methods (i.e., no existing single procedure is capable of identifying the presence of all pesticides that can be present on or used in food), FDA cannot routinely test each food sample for all pesticides that may be present on food it collects.

Limited Value of Single-Residue Methods

As part of the tolerance-setting process,[3] the pesticide manufacturer must submit an analytical method to EPA that is capable of detecting and measuring residues of the pesticide at the tolerance level on the food commodity for which a pesticide registration is being sought. Single-residue methods are developed and submitted to meet this requirement. Pesticide manufacturers do not have to submit a method if EPA decides to exempt the pesticide from a tolerance requirement.

FDA prefers not to use single-residue methods as the basis for routinely analyzing foods for pesticide residues because the tests usually take at least as much time to conduct as do multiresidue methods and can detect only a single pesticide on a single sample for which a tolerance has been established. FDA laboratory officials stated that because of time and resource constraints, it is impractical to use single-residue methods to routinely analyze all food samples for each and every pesticide that might be present. These officials also said that not every pesticide must be routinely tested because some pesticides on the list are no longer produced, do not pose enough of a health hazard, or will not leave residues. According to program officials, FDA would have to either significantly reduce the amount of sampling and testing that could be accomplished or drastically increase resources if single-residue tests were to be routinely used. Consequently, single-residue methods are generally restricted to situations in which either FDA (1) conducts special surveys on certain pesticides, (2) confirms the presence of illegal residues for those pesticides which are detected by a multiresidue method, or (3) knows or suspects that a specific pesticide has been misused.

Multiresidue Methods Are Preferred but Cannot Detect Most Pesticides

FDA prefers using multiresidue methods that are capable of detecting and identifying, on a single sample, large numbers of pesticides having similar chemical and physical properties. Multiresidue methods are most cost-effective in analyzing individual food samples for a large number of

[3]See GAO/RCED-86-125, ch. 3.

pesticides. FDA has developed five comprehensive multiresidue methods that are most commonly used to detect illegal pesticide residues. Each of the five methods is capable of covering different pesticides on different commodities. These multiresidue methods are capable of detecting different classes of chemical families such as organochlorines, organophosophorus, carbamates, organonitrogens, and organosulfurs. The number of pesticides that can be detected by each method ranges from 24 to 123, as shown in table 3.1.

Table 3.1: Pesticides Covered by FDA's Most Commonly Used Multiresidue Methods

Multiresidue methods developed by FDA	Number of pesticides detected by each method
Non-fatty	123
Luke	121
Fatty	97
Storhrerr	61
Krause	24

FDA laboratory officials said that because of time, personnel, and equipment constraints they normally use one multiresidue method when analyzing food and do not routinely analyze each food sample for all pesticides that could be detected by the method used. According to these officials, the decision about which pesticides will be tested under the method used depends on which pesticides

- are registered for use on the crop in the state where it is grown,
- are known to be or suspected of being used (based on information available to FDA from EPA, states, and other sources), and
- have been found in prior testing either because of misuse or environmental contamination.

The decisions are also influenced by other factors such as the type of crop being sampled, known pest problems, and climatic conditions.

The most significant limitation with the five multiresidue methods FDA most commonly uses is that cumulatively they are known to detect fewer than one-half of the pesticides that FDA has identified as possibly appearing on food. In combination, the five multiresidue methods can detect 203 (40.9 percent) of the 496 pesticides identified by FDA. This leaves 293 (59.1 percent) pesticides that cannot be detected by the five

multiresidue methods. For these 293 pesticides, other methods must be used.

Historically, the Congress has expressed concern about FDA's failure to test for a large number of pesticides, especially those that may be potentially harmful to human health. In 1978 the Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, held hearings on the extent to which cancer-causing chemicals appeared in food and expressed concern that FDA was not testing for many pesticides by using other testing methods. The Subcommittee recommended, among other things, that FDA selectively use single-residue methods to test for pesticides that are not detected by multiresidue methods.[4] FDA agreed with the Subcommittee's recommendations and in 1979 concluded that it should selectively test for those pesticides which are not detected by multiresidue methods according to their potential health risk and usage.

FDA Has Not Completed Classifying the Health Hazards of Most Pesticides

Beginning in 1979, FDA initiated the surveillance index program to classify pesticides according to their health hazards in order to identify those pesticides that need testing under the pesticide monitoring program. The classifications are based on such factors as the pesticide's toxicity, use, and potential for leaving a residue. During the 6 years since the program began, FDA has developed classifications for 186 of the 496 pesticides it has identified. The remaining 310 pesticides, most of which are not detected by any of FDA's five commonly used multiresidue methods, have not been classified under the surveillance index program. FDA uses the surveillance index classifications as a guide for expanding the capability of multiresidue methods and initiating special surveys, and as guidance for district offices to consider when testing food for pesticide residues.

In selecting pesticides for assessment and classification under the surveillance index program, FDA gave priority to those pesticides that were not covered by its multiresidue methods and were undergoing special review by EPA.[5] FDA's classifications are based on information that FDA

[4]Cancer-causing Chemicals in Food, report by the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce, December 1978.

[5]EPA's special review is a process for reviewing a pesticide's risks and benefits if the pesticide poses a special concern due to a specific health or environmental problem (e.g., suspected of causing cancer, birth defects, or genetic effects). At the conclusion of special review, EPA may decide to continue, restrict, or cancel pesticide uses under consideration. For a detailed discussion of the special review process, see GAO/RCED-86-125, ch. 7.

receives from EPA about the health risks of the pesticides. In classifying pesticides, FDA scientists analyze a number of factors, including the pesticide's toxicity, usage in terms of poundage and crop, potential for leaving a residue on food crops, and persistence in the environment.

Through November 1985, FDA had developed surveillance index classifications for 186 pesticides. Table 3.2 defines the five surveillance index classifications FDA uses and shows the number of pesticides in each class that can and cannot be detected by at least one of FDA's five commonly used multiresidue methods.

Table 3.2: Classification of Pesticides Under the Surveillance Index Program

Classification	Number of pesticides assessed	Number known to be detected by at least 1 multiresidue method	Number not known to be detected by any of the 5 multiresidue methods
Class I - the pesticide represents a high health hazard on a toxicological basis. Based on both demonstrated adverse effects in animals and/or humans and anticipated dietary exposure, the pesticide warrants immediate inclusion in the monitoring program on a continuing basis.	9	1	8
Class II - a high health hazard has not been demonstrated, but there is evidence of possible high risk toxicity effects combined with the potential for significant human dietary exposure. The potential hazard is sufficient to warrant a temporary inclusion of the pesticide in the monitoring program as soon as possible, and to continue until exposure to the pesticide is more clearly defined or until additional toxicity data, exposure data, or EPA actions indicate assignment to a different class.	34	20	14
Class III - a moderate hazard profile, based on weighing both toxicity and dietary exposure factors, warrants the pesticide's periodic inclusion in the monitoring program over the long term due to the chance of exceeding tolerances or the acceptable daily intake.	48	37	11
Class IV - sufficiently low hazard potential, from the toxicological and/or exposure standpoint, justifies only intelligence-related monitoring efforts.	82	40	42
Class V - very little potential hazard, due to low toxicity or minimal possible exposure, warrants exclusion of the pesticide from routine monitoring efforts at this time.	13	7	6
Subtotal of pesticides assessed	186	105	81
Number of pesticides not assessed	310	98	212
Total number of pesticides	**496**	**203**	**293**

Most pesticides that FDA has classified can be detected by one or more of the five commonly used multiresidue methods. For the 186 pesticides that have been classified:

- 105 are known to be detected by at least one of the five multiresidue methods; 58 of the 105 pose a moderate to high health hazard while 47 pose little to no health hazard.

- 81 are not known to be detected by any of the five multiresidue methods; 33 of the 81 pose a moderate to high health hazard while 48 pose little to no health hazard.

Of the remaining 310 pesticides that have not been classified under the surveillance index program, 135 have permanent tolerances established by EPA while the other 175 do not. FDA plans to complete surveillance indexes for the 135 pesticides with permanent tolerances at a rate of 30 to 50 pesticides per year. At the planned rate of completion, it will take FDA between 2.7 and 4.5 years to complete the assessment and classification of these 135 pesticides.

According to the program director, FDA does not plan to assess and classify the 175 pesticides without permanent tolerances unless it learns of a significant residue or toxicity problem associated with the use of a pesticide. Program officials said that they believe that most of the potentially dangerous pesticides have already been classified. These officials also said that many of the pesticides that have not yet been classified probably pose no substantial health hazard to humans, while a few that have not yet been classified pose such well-known health hazards that they do not need to be classified. Pesticides in the latter category include chlorinated hydrocarbons (e.g., DDT, aldrin, and dieldrin) which were suspended for most uses by EPA in the 1970's but which already are detected by the multiresidue methods.

FDA's classifications are subject to change as more information becomes available on individual pesticides. FDA's assessments depend upon the quantity and quality of toxicological and chemistry residue information that EPA has in its files. EPA is reassessing most agricultural pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act. Reassessments may require pesticide registrants to submit additional toxicity testing and chemistry residue data; these data may result in changes to current knowledge about existing pesticides. However, EPA will not be able to reassess all pesticides until the 21st century.[6]

[6]See GAO/RCED-86-125, ch. 2.

Infrequent Testing Is Done on Pesticides FDA Requires to Be Tested Either Continuously or Periodically

FDA uses the surveillance indexes as a guide in determining which pesticides should be included as special surveys and as guidelines for the districts to use when considering which pesticides should be routinely tested for when they are likely to be used on individual food commodities. FDA has identified 33 pesticides that are not detected by any multiresidue method but that require continuous to periodic monitoring because of their potential health hazard to humans. However, FDA has not established criteria specifying what level of testing is required for continuous or periodic monitoring. FDA data indicate that, with three exceptions, most pesticides received little or no testing in fiscal years 1979-85. Also, we found through the individual case studies of apples, cabbage, corn, grapefruit, grapes, lettuce, and oranges that FDA laboratories during fiscal year 1984 had not tested for a number of pesticides that FDA has identified as requiring continuous or periodic monitoring, because of their health hazard and likely use, if they cannot be detected by a multiresidue method. Laboratory officials cited time and resource constraints as principal reasons why they did not test for these pesticides.

Extent of FDA's Testing for Potentially Hazardous Pesticides Through Special Surveys

Although FDA can detect, through the multiresidue methods, 58 of 91 pesticides that are classified as posing a moderate to high health hazard, either single-residue or other less comprehensive multiresidue methods must be used to detect the remaining 33 pesticides. Table 3.3 lists these 33 pesticides by surveillance index classification and includes EPA estimates of the number of pounds used by American agriculture.

Table 3.3: Pesticides in Classes I, II, and III That Are Not Covered by FDA's Most Commonly Used Multiresidue Methods

	EPA nationwide estimates of pounds used by American agriculture (Millions)
Class I	
Calcium arsenate	1–2
Copper arsenate	1–2
Lead arsenate	1–2
Magnesium arsenate	1–2
Orthoarsenic acid	1–2
Potassium arsenite	1–2
Sodium arsenate	1–2
Sodium arsenite	1–2
Class II	
Benomyl	2–3
Carbon tetrachloride	<1
Daminozide	<1
Ethylene dibromide	<1
Maleic hydrazide	4–7
Mancozeb	9–12
Maneb	5–6
Metiram	2–3
Paraquat	5–6
Pentachlorophenol	<1
2,4,5-T	<1
Silvex	<1
Thiophanate-methyl	<1
Zineb	1–2
Class III	
Chloroxuron	<1
Cyhexatin	<1
Dibromochloropropane	<1
Dinoseb	7–8
Diuron	2–3
Formetanate hydrochloride	<1
Picloram	<1
MCPA	5–8
Methyl bromide	<1
Oxyfluorfen	<1
2,4-D	<1

Note: < means "less than."

Data provided by FDA for fiscal years 1979-85 indicated that 19,364 domestic food samples were analyzed specifically for 1 or more of 28 of the 33 pesticides. The five remaining pesticides were not tested at all. Table 3.4 shows the frequency with which these pesticides were tested on food samples between fiscal years 1979 and 1985.

Table 3.4: Frequency of Testing, Fiscal Years 1979-85

Pesticide tested in food samples	Number of food samples tested
EDB	8,546
Carbon tetrachloride	7,537
Pentachlorophenol	1,570
Eight compounds in class I	355
MCPA, Silvex	269
Benomyl and thiophanate-methyl	227
2,4-D and 2,4,5-T	198
Methyl bromide	145
Cyhexatin	137
Daminozide	125
Paraquat	87
Dibromochloropropane	77
Mancozeb, maneb, metriam, and zineb	76
Picloram	9
Maleic Hydrazide	6
Dinoseb, diuron, oxyfluorfen, chloroxuron, and formetanate hydrochloride	0
Total	**19,364**

As table 3.4 shows, FDA concentrated its testing on three pesticides (i.e., EDB, carbon tetrachloride, and pentachlorophenol). A total of 17,653 samples (about 91 percent of the 19,364 samples) were tested for one or more of these three pesticides. Between 6 to 269 samples were tested for one or more of 17 pesticides while 355 samples were tested for 8 pesticides, and no samples were tested for 5 pesticides.

Ideally, FDA program officials would like to be able to test for all pesticides using their multiresidue methods. However, until current methods can be expanded, FDA will have to continue to analyze foods for many pesticides using alternative test methods. According to FDA, expanding multiresidue methods is a time-consuming and costly process. For example, FDA began using multiresidue methods in the 1950's and is still able to detect less than one-half the pesticides that have the potential for appearing as residues in food. Although FDA has various in-house

projects to include more pesticides in these methods, this research is limited by resources and other competing priorities, according to program officials.

A recent requirement that EPA imposed on pesticide manufacturers should aid FDA efforts to expand the capabilities of its multiresidue methods. In October 1984, EPA began requiring pesticide manufacturers, as part of the tolerance-setting process, to conduct residue tests for their pesticides using an FDA multiresidue method and to submit the results as part of the tolerance petition. This requirement is designed to encourage pesticide manufacturers to find ways to detect pesticides by using an FDA multiresidue test instead of developing single-residue tests. FDA officials said that this requirement should facilitate their ability to detect the newer pesticides being marketed using its most commonly used multiresidue methods.

FDA Laboratories Do Not Routinely Test for Potentially Hazardous Pesticides If They Are Not Detected by Existing Multiresidue Methods

According to FDA laboratory officials, most domestic food samples are generally analyzed using one of five multiresidue methods.[7] Our review of FDA's testing of seven commodities indicates that FDA laboratories did not generally test for pesticides that were not detected by the multiresidue method used by the laboratory and that FDA has concluded require continuous or periodic testing because of their potential health hazards.

The extent to which food samples are tested for potentially harmful pesticides that might be used varied by commodity and laboratory. For example, the multiresidue method used by the Atlanta laboratory detected those pesticides posing a moderate to high health hazard that were registered for use on oranges and grapefruit in Florida. On the other hand, the multiresidue methods used by the Seattle, Dallas, Minneapolis, San Francisco, and Los Angeles laboratories could not detect some of the potentially harmful pesticides that are registered or used on either apples, lettuce, cabbage, corn, or grapes in various states under their jurisdiction. However, these five laboratories did not use alternative tests to analyze food samples for these pesticides.

Our review of records and our discussions with district officials regarding these five crops found that no alternative tests were used

[7] If the initial analysis indicates the presence of a significant amount of a particular pesticide, the laboratory may use another FDA multiresidue method or single-residue method to confirm its presence.

during fiscal year 1984 to analyze food for moderately to highly hazardous pesticides that are not detected by the laboratories' multiresidue methods. Several examples are illustrative.

- The multiresidue method used by Detroit could detect 12 of the 54 pesticides recommended for use on apples in Michigan. Of the remaining 42 pesticides, 19 represent a moderate to high health hazard requiring periodic or continuous monitoring. The Detroit laboratory did not use alternative tests to analyze apples for any of these pesticides during fiscal year 1984, although all 19 pesticides were recommended for use in Michigan and three of these pesticides represent about 36 percent of Michigan's restricted-use pesticide sales.[8]
- The multiresidue method used by the Los Angeles and San Francisco laboratories cannot detect 34 of the 76 pesticides registered for use on grapes in California. Two of these 34 pesticides—sodium arsenate and methyl bromide—are widely used in California; according to the most recent data available, about 900,000 pounds of these two pesticides combined are used annually on the state's grapes. FDA has classified sodium arsenate as a high health hazard warranting continuous monitoring and methyl bromide as a moderate health hazard warranting periodic monitoring. FDA officials in both laboratories said that neither methyl bromide nor sodium arsenate is tested for on grapes because both dissipate rapidly after application.
- The multiresidue methods used by the Minneapolis laboratory could not detect 24 pesticides recommended for use on corn in Illinois. FDA classified 9 of the 24 pesticides as posing a moderate to high health hazard warranting periodic or continuous monitoring. The Minneapolis laboratory did not test for any of these pesticides on corn during fiscal year 1984.
- The multiresidue method used by Dallas could not detect 13 of 51 pesticides registered for use on lettuce and 17 of 60 pesticides registered for use on cabbage in Texas. Three of the 13 pesticides are used on lettuce and 2 of the 17 pesticides are used on cabbage. These pesticides were classified by FDA as posing a high health risk warranting continuous monitoring. The Dallas laboratory did not test any of its lettuce or cabbage samples for these pesticides during fiscal year 1984.

Laboratory officials said that they do not routinely test for pesticides that FDA has classified as posing a moderate to high health hazard if

[8]Pesticides are classified as being for restricted use because of their high potential hazard to the individuals who apply them and to the environment if they are not properly applied. These restricted-use pesticides can be applied only by individuals who have been certified to use them by either the state or EPA.

they are not detected by multiresidue methods used by the laboratory. According to these officials, such pesticides are not routinely tested because it takes time to set up equipment and perform the tests. Single-residue methods are not used to supplement the multiresidue method used by the laboratory because such testing would take considerable time to perform and can detect only a specific pesticide. Laboratory officials said that if they were to deemphasize the use of multiresidue methods in testing for illegal pesticide residues, less testing coverage would be provided and, consequently, the public would be even less protected from exposure to illegal pesticides than it currently is.

FDA headquarters has recognized the importance of concentrating some coverage on pesticides posing a potential health hazard by providing annual guidelines to the districts which specifically require them to consider this factor when testing. However, FDA laboratories continue to rely on multiresidue methods and do not give a high priority to testing for pesticides that FDA scientists have concluded pose a significant enough health hazard to require continuous or periodic monitoring.

Conclusions

FDA faces an enormous challenge in testing food samples for pesticide residues that might be present on food. Because of time and resource constraints, as well as limitations with testing methods, FDA cannot routinely test food for the large numbers of pesticides that can be used on or are present in food. FDA generally tests individual food samples using one of its five approved multiresidue methods; these methods can detect only a small portion of the 496 pesticides that might be present. It seldom uses other tests for pesticides that cannot be detected by the multiresidue methods, including a number of pesticides that FDA has concluded require continuous or periodic testing because of their potential health hazard.

Despite the limitations of the multiresidue methods, we believe that FDA should continue to (1) rely on these methods as the basis for testing food for illegal pesticide residues and (2) expand the number of pesticides that can be detected by these methods. However, until a comprehensive capability exists to test for most pesticides, we believe that FDA needs to require more testing for those pesticides that are not detected by the multiresidue methods but that FDA had determined require continuous or periodic testing. Also, there is a need for FDA headquarters to spell out for its laboratories specific criteria for the level of testing that is required for continuous and periodic monitoring.

We believe that FDA's laboratories should test food samples for pesticides that FDA has stated require continuous or periodic testing when there is a likelihood that they are being used locally, even if this requires testing in addition to the multiresidue testing. Until these pesticides are tested on a more regular basis, FDA's ability to deter the marketing of food with illegal residues of these high and moderate hazard pesticides will be quite limited.

Recommendation to the Secretary of Health and Human Services

We recommend that the Secretary direct the FDA Commissioner to establish specific criteria for the level of testing that is required for continuous and periodic monitoring and require FDA laboratories to test in accordance with such criteria.

FDA Faces Legislative Limitations in Preventing the Marketing of Adulterated Food

Under FDA's monitoring program, the vast amount of domestically produced food is not sampled and analyzed for illegal pesticide residues; thus, the probability that FDA will find a grower marketing food with illegal pesticide residues is rather low. It is therefore important that, when FDA does find such food, it must have authority to pursue regulatory actions that serve as disincentives for growers to market food containing illegal pesticide residues. The most effective disincentives are either to prevent food that FDA finds to contain illegal pesticide residues from being marketed or to penalize growers when FDA cannot prevent the marketing of such food.

FDA cannot prevent most food that it identifies as being adulterated with illegal pesticide residues from being marketed because the food moves so quickly into the marketplace. In many cases, the food has already been sold before FDA completes the analysis needed to confirm the presence of illegal pesticide residues. A contributing factor is that FDA lacks the authority to detain domestic food suspected of containing illegal residues while it is seeking either a seizure or injunction order to remove the food from the market. Since FDA lacks detention authority, it often asks (1) growers to voluntarily destroy or remove the produce or (2) states to embargo the food. However, even in those cases where FDA does get grower or state cooperation, it is often unable to remove 100 percent of the adulterated food from the market.

FDA also does not penalize growers who market food containing illegal pesticide residues because its authority is limited to pursuing criminal penalties. FDA does not pursue criminal penalties in pesticide-related cases because of the difficulties involved in gathering needed evidence. According to some FDA officials, civil penalties would be a more effective deterrent than criminal penalties mainly because of the difficulties involved in gathering sufficient evidence to pursue criminal penalties. However, at the present time, FDA lacks the authority to issue civil penalties against growers in pesticide-related cases. Because of the problems FDA has in removing adulterated food from the market and the difficulties involved in pursuing criminal penalties, we believe civil penalty authority is needed for FDA to effectively deter the marketing of food with illegal pesticide residues.

Most Food Containing Illegal Pesticide Residues Is Not Removed

FDA is not successful in preventing most food that it finds to contain illegal pesticide residues from being sold. In the nine districts we visited, we examined 222 cases between October 1, 1983, and June 30, 1985, in which samples were initially reported as being adulterated with illegal pesticide residues. Of this number, 17 were subsequently found not to be adulterated while 26 were not within FDA's jurisdiction because the food was not being shipped in interstate commerce. Consequently, FDA had jurisdiction over 179 cases involving the interstate marketing of food found to contain illegal pesticide residues. Table 4.1 shows the disposition of these 179 cases.

Table 4.1: Disposition of Adulterated Food Found by FDA

	Number of cases
All or some portion of the food was seized by FDA	3
All or some portion of the food was voluntarily destroyed by the grower	64
All or some portion of the food was embargoed by the state	5
Food was not available to prevent sale	107
Total	**179**

In 107 of the 179 cases in which FDA found that food contained illegal pesticide residues, it did not take any action to prevent food from reaching the market because the food had already been sold. In the other 72 cases, at least some portion of the adulterated food was removed as a result of either FDA seizures, state embargo, or voluntary removal by the growers. Table 4.2 shows the percentage of food recovered in these 72 cases. As indicated, all of the adulterated food was recovered in only 19.4 percent of the cases.

Table 4.2: Success in Removing Food Found to Contain Illegal Pesticide Residues

Percent of food removed	Growers or states cooperated in removing food	FDA seized the food	Total number of cases	Percent of total
100	13	1	14	19.4
90-99	2	0	2	2.8
80-89	1	0	1	1.4
50-79	2	1	3	4.2
25-49	3	1	4	5.6
0-24	3	0	3	4.2
Portion of food removed is unknown[a]	45	0	45	62.5
Total	**69**	**3**	**72**	**100.1[b]**

[a]We were unable to determine the percentage of food recovered in 45 cases because FDA records did not contain all the information necessary to calculate the percentage of food removed

[b]Does not equal 100 percent due to rounding

FDA Rarely Uses Legislative Authorities in Pesticide-Related Cases

For various reasons, FDA rarely relies on its legislative authorities to prevent the interstate shipments of domestic food containing illegal pesticide residues.

The FD&C Act gives FDA the following legal authorities to use in preventing the interstate marketing of domestic food containing illegal pesticide residues:

- FDA may initiate seizures to remove interstate shipments of food containing illegal pesticide residues under Section 304 of the FD&C Act. A complaint for seizure is filed by the U.S. attorney's office within the appropriate district court. The court then orders a U.S. marshal to seize the adulterated product. Seizures are limited to the specific quantity and location of products which FDA identifies in the seizure complaint.
- FDA may seek court-ordered injunctions to prevent shipments of food containing illegal pesticide residues from being marketed through interstate commerce. Injunctions are authorized under Section 302 of the FD&C Act and are processed through the courts similar to seizures.
- FDA may seek criminal penalties against those responsible for shipping food containing illegal pesticide residues. Under Section 303 of the FD&C Act, fines up to $1,000 per violation and/or up to 1 year's imprisonment can be assessed on the first conviction involving a violation of the act, and up to $10,000 per violation and/or up to 3 years' imprisonment can be assessed on a second conviction involving a violation of the act or for

a first violation if it was committed with the intent to defraud or mislead. The Criminal Fine Enforcement Act of 1984 (Public Law 98-596), which went into effect on January 1, 1985, provided authority to impose significantly higher fines. The amount assessed can vary depending upon the circumstances involved. For instance, the new act allows for fines of $100,000 and higher.

FDA may also issue written warnings in cases where it decides that such actions best serve the public interest.

In only 3 of the 179 violations we reviewed did FDA seize some portion of the food containing illegal pesticide residues. FDA districts did not seek injunctions or criminal penalties in any of the violations we reviewed. FDA issued written warnings in 29 of the 179 violations we reviewed.

Because FDA lacks detention and civil penalty authorities, it relies on the grower or producer to voluntarily destroy, recall, or reprocess food. It also relies on obtaining state assistance in holding or destroying the food. FDA rarely relies on existing legislative authorites because, according to FDA district officials, they are not well suited for application to most pesticide-related cases.

Seizures

FDA rarely uses its seizure authority to remove food containing illegal pesticide residues from the market. Our review of 179 violations that occurred between October 1, 1983, and June 30, 1985, indicates that FDA initiated seizures in 12 violations and seized some portion of the food in 3 violations. In the remaining nine violations, growers agreed to voluntarily destroy or remove the food so that FDA did not have to seize the food. Table 4.3 provides information on the three seizures and the extent to which food containing illegal pesticide residues was removed from the market.

Table 4.3: Seizure Actions and Results

District office	Product seized	Date sample collected	Date seizure accomplished	Days elapsed	Product available		Percent recovered
					Originally	Recovered	
Chicago	Peas	07/21/84	08/06/84	16	700 lbs	700 lbs	100
Minneapolis	Wheat	04/25/84	06/01/84	37	200,000 lbs	100,000 lbs	50
Minneapolis	Chub fish	11/02/84	01/10/85	69	1,610 lbs	250 lbs	16

As table 4.3 indicates, FDA was able to seize all of the food in one of the three cases. In the remaining two cases, FDA seized 50 and 16 percent of the food, respectively.

FDA's process for seizing food adulterated with illegal pesticides is as follows:

- The FDA district determines that the food contains illegal pesticide residues.
- The district submits a written recommendation for seizures to FDA headquarters.
- FDA headquarters reviews the district's recommendation to assure that the food is in violation and that the seizure recommendation is consistent with FDA policy.[1]
- The case is referred to the appropriate U.S. attorney's office for action.
- The U.S. attorney petitions the U.S. District Court for a seizure order.
- The court reviews the petition and issues a court order authorizing the U.S. marshal to seize the adulterated food.
- The U.S. marshal seizes the food.

According to FDA program officials, the producer of the adulterated food is under no obligation to halt its marketing until the U.S. marshal seizes the food. In a September 1984 report,[2] on the basis of our review of 202 FDA seizures of food products, we reported that the average time taken to seize products was 65 days. FDA's review process averaged 41 days, ranging from 5 to 206 days. An additional 24 days on average, ranging from 1 to 150 days, was needed to process the seizure through the U.S. attorney's office and the court. Obviously, the more time that elapses between the time FDA collects a sample of the food and the court authorizes seizure, the less likely it is that the food will be available for seizure. If FDA were authorized to detain the food at the time the sample is collected, FDA could prohibit the grower from marketing the food until it completes its laboratory test and obtains the seizure order, thus increasing the likelihood that more adulterated food will be available for removal.

FDA district officials said that seizures are not pursued because FDA does not have the authority to detain domestic food that it finds to contain

[1]Under certain conditions districts can bypass FDA headquarters review and go directly to the U.S. attorney (referred to as direct reference seizure action).

[2]Legislative Changes and Administrative Improvements Should Be Considered for FDA to Better Protect the Public From Adulterated Food Products (GAO/HRD-84-61, Sept. 28, 1984)

illegal pesticide residues until it can obtain a court authorization to seize the food.

Injunctions

The act gives FDA authority to seek injunctions against farmers, manufacturers, or shippers who either continue shipping food containing illegal pesticide residues through interstate commerce or who have a history of pesticide misuse. FDA has concluded that injunctions cannot be pursued when one or more of the following conditions exist:

- Follow-up investigations show that the food has been completely harvested or marketed.
- Residues are no longer above tolerance levels.
- Individuals voluntarily withhold further shipments of food.
- State officials are requested by FDA to embargo the remaining quantities of food.

FDA did not seek injunctions in any of the cases we reviewed. One or more of the conditions cited by FDA for not pursuing injunctions applied to all the violations we reviewed.

Criminal Penalties

In addition to seeking seizures and injunctions, FDA can also pursue criminal penalties for serious violations of the act. Criminal penalties are probably the most serious action FDA could take against growers or processors who knowingly market food containing illegal pesticide residues. District officials said that they do not recommend pursuing criminal penalties in pesticide-related cases because the growers usually do not have histories of continuing to ship adulterated food.

FDA stated it is difficult to collect sufficient evidence needed for criminal prosecution in pesticide-related cases. According to the 1979 internal evaluation of the pesticide monitoring program, a period of months may elapse between the time the pesticide is applied and the commodity is harvested and shipped in commerce, and consequently such evidence is virtually impossible to obtain. As a result, a criminal case is difficult to support unless an individual has a history of producing and marketing food adulterated with residues by failing to follow good manufacturing or agricultural practice.

Furthermore, it can be costly for FDA to pursue criminal penalties. For instance, in 1984 we reported that FDA officials estimated that it takes

about 400 staff hours or $8,000 to $10,000 to develop a criminal case.[3] Further, a case that goes to trial may cost FDA an additional $8,000 to $10,000 to prosecute.

Written Warnings

The act gives FDA authority to issue written warnings in those cases where it believes the public interest is best served by such an action. FDA can use written warnings to inform growers that their food contained illegal pesticide residues and require recipients to take corrective action to prevent a future recurrence. FDA regulations specify two types of written warnings that can be used.

- A regulatory letter is issued when FDA concludes that a violation is serious enough to warrant immediate action such as seizures, injunctions, or criminal penalties against firms or individuals if corrective action is not taken. Letters require firms or individuals to provide FDA with written responses, usually within 10 days, detailing actions to prevent future violations from recurring. Because a letter commits FDA to take action if the written response is inadequate, headquarters approval may be required.
- A notice of adverse findings is issued when FDA concludes that a violation is not serious enough to warrant immediate action againt firms or individuals but is serious enough to warrant some type of written notice. Notices require firms or individuals to provide FDA with written responses, usually within 30 days, detailing actions to prevent future violations from recurring. Notices do not commit FDA to future action if the response is not satisfactory and they do not require headquarters approval. Notices can be used either alone or in conjunction with other regulatory actions.

We found that the districts infrequently used written warnings in pesticide-related cases.

- In 1985 Dallas issued letters on two violations after FDA district officials detected dieldrin, a banned pesticide, in oils used in animal feed produced by two firms. Both firms agreed to stop buying the oils.
- Four districts (Atlanta, Dallas, Los Angeles, and Seattle) issued 14 notices covering 27 violations. Because FDA files did not contain complete information, we were unable to determine what action if any was taken by growers. However, in the cases where files did exist, growers

[3]See GAO/HRD-84-61.

agreed to either stop using the pesticide or growing the particular commodity.

Written warnings are seldom used because most violations are either not repeated or not serious enough to warrant corrective action, according to FDA district officials.

FDA laboratory guidelines require that, when FDA finds that a sample contains an illegal pesticide residue, a copy of the results be sent to the farmer indicating the type and amount of pesticides found and a notice that the sample is in violation of existing law. We reviewed compliance with this requirement in three FDA districts and found that it was generally being complied with. FDA officials said that sending these laboratory results to growers serves to deter future misuse because it lets the farmer know that an illegal residue was found on the crop and that there might be some follow-up sampling and testing of the crop.

Laboratory Analysis Cannot Be Accomplished in Time to Take Enforcement Action

Since most raw agricultural commodities move very rapidly from the farmer to the consumer, the amount of time it takes to analyze food samples for illegal pesticide residues affects FDA's chances of getting adulterated food off the market. The quicker FDA is able to complete the analysis needed to prove that illegal pesticide residues are present, the greater the possibility that FDA will be able to remove adulterated food from the market. In most cases we reviewed, the food was sold before FDA completed its analysis.

According to a 1983 FDA internal study, sample analysis usually needs to be completed within 24 to 48 hours after the samples are collected for FDA to be able to remove the food from commerce before it is consumed. For most of the violative samples we reviewed, considerably more than 48 hours elapsed between the date the food samples were collected and the date the laboratory conducted the analysis. For the 179 violations, an average of 18 calendar days elapsed between the date the sample was originally collected and the date the sample was analyzed. About 83 percent of the violations took longer than 2 days and about 47 percent took longer than 10 days.

In the 107 cases in which food was not available for FDA to take any action, the average processing time was about 27 calendar days between when the sample was collected and the analysis was conducted. Approximately 92 percent of the 107 violations took more than 2 calendar days,

and about 71 percent took more than 10 calendar days. Table 4.4 shows the ranges for all 107 violations.

Table 4.4: Processing Time for 107 Violations Where FDA Took No Action

Processing time	Number of samples	Percent of total samples
1-2 days	7	6.5
3-5 days	8	7.5
6-10 days	16	15.0
11-20 days	23	21.5
21-50 days	41	38.3
50+ days	12	11.2
Total	**107**	**100.0**

Forty-five of the 107 violations occurred in Minneapolis and Chicago as part of FDA's efforts to monitor fish in Lake Michigan for contamination with pesticides known as chlorinated hydrocarbons. An average of 33 calendar days in Chicago and 38 calendar days in Minneapolis elapsed between the date FDA collected the fish samples and the date they were analyzed. These districts make almost no effort to try and remove violative fish from the market because, according to FDA officials, most fish are caught and sold the same day. District officials stated that they did not consider the long processing time for fish samples to be a problem. In their opinion, the results of the analysis make fish safer because they use these results to ban fishing in various parts of the lake until test results show that residues found in fish are low enough to be acceptable for health purposes.

Most food samples take more than a few days to analyze and most of that time is spent awaiting laboratory analysis. This occurs because food samples collected for pesticide testing must compete with foods being analyzed for other forms of adulteration, as well as other substances that must be tested. Also, because most samples are collected without prior knowledge or indications that illegal pesticide residues are present, it is impossible for FDA to predict beforehand which samples will contain illegal pesticide residues.

Initiatives to Enhance FDA's Ability to Deter the Marketing of Adulterated Food

FDA's 1979 evaluation of the pesticide program concluded that inadequate regulatory authority is a contributing factor to FDA's inability to prevent the marketing of adulterated food. Consequently, the study concluded that to better control interstate shipments of domestic food, the agency needs to have the authority to (1) detain domestic food it suspects of being adulterated and (2) pursue civil penalties in lieu of criminal penalties.

Precedent Exists for Detention Authority

FDA is frequently unable to prevent the shipment of domestic food it suspects of being adulterated with illegal pesticide residue. If FDA had detention authority over domestic food, it could order a grower to hold the suspected commodity until it could obtain seizure approval.

Although the act does not give FDA authority to detain domestic food, it does give FDA authority to detain imported food. Section 801 of the act authorizes FDA to refuse admission into the United States of any imported food it determines to be adulterated. Such products are to be destroyed, reexported or, in appropriate cases, allowed admission if other action brings them into compliance with the act. Under this authority FDA can detain food that it suspects contains illegal pesticide residues, either from past experience or initial sampling results.

According to most FDA district officials, the lack of detention authority over domestic foods suspected of containing illegal residues made it difficult for them to pursue seizures and injunctions because of the time involved in obtaining the orders needed to remove the food. They believe that detention authority over domestic foods, similar to that over imports, could improve their ability to control the marketing of domestic food containing illegal pesticide residues. If FDA had such authority, it could order the farmer not to ship potentially adulterated food until FDA could pursue seizure action.

In September 1984, we reported on FDA's total food safety program and concluded that FDA could prevent greater amounts of adulterated food from getting on the market if it had legislative authority to detain adulterated food.[4] As a result we proposed that the Congress amend the FD&C Act to provide FDA with detention authority over domestic food. Since detained products cannot be moved during the detention period, this authority would help FDA prevent potentially adulterated food from

[4]See GAO/HRD-84-61.

getting to market while recommended legal actions are being approved and implemented.

In fiscal years 1980 and 1983, FDA introduced detention proposals as part of omnibus bills to amend the act. However, Congress did not act on these omnibus bills.

Civil Penalties Can Aid FDA in Certain Circumstances

When FDA finds that food contains illegal residues, it often cannot take action to remove it because it has been sold. In these situations, FDA officials believe that the agency needs authority to impose civil penalties (i.e., monetary fines) against growers who shipped the food into interstate commerce. Such penalties would serve as a deterrent to the marketing of adulterated food because they would involve some economic loss to the grower.

At present FDA can pursue only criminal penalties. But in many pesticide-related cases, criminal penalties are inappropriate because, according to some FDA officials, criminal penalties can be applied only when FDA can demonstrate criminal misconduct on the part of a grower or producer. Such violations can be very difficult to prove. On the other hand, civil penalties could provide FDA with a recourse against growers who ship food containing illegal residues.

As a result of its 1978 hearings, the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce recommended that FDA be provided with authority to impose civil penalties on growers who send contaminated animals to slaughter. FDA's 1979 internal evaluation of the program endorsed this recommendation but wanted the authority expanded to include all food and animal feed. According to some FDA district officials, civil penalties would be more appropriate than criminal penalties in most pesticide-related cases.

FDA introduced civil penalty provisions as part of its fiscal year 1980 omnibus proposal for amending the FD&C Act. However, like detention proposals, the civil penalty proposal has not been acted on by the Congress. FDA has not submitted any proposals for civil penalties since that time.

Conclusions

To meet its legislative mandate, FDA must be able to quickly identify food that contains illegal pesticide residues and prevent the food from reaching the market. According to FDA, food samples should be analyzed

within 24 to 48 hours after they are collected. However, in the 179 violations we reviewed, an average of 18 calendar days elapsed between the day samples were collected and the day the analysis was done. Only 7 of these 179 violations were analyzed within 24 to 48 hours after they were collected. To meet this goal, FDA would probably have to substantially increase resources devoted to analyzing samples for pesticide residues.

Although timeliness is a factor affecting FDA's ability to take action needed to prevent food from reaching the public, additional legislative authority would probably enhance FDA efforts to more effectively protect the consumer from being exposed to such food. Detention authority would be useful to FDA when it decides to pursue a seizure action rather than depend on the voluntary cooperation of either the grower or the state. We agree and we continue to support the proposal made in our 1984 report that the Congress provide FDA with detention authority for domestic food which it finds to be adulterated.

FDA lacks an effective means of penalizing growers when food containing illegal pesticide residues is marketed and cannot be recovered. We believe that civil penalty authority would provide FDA with an additional deterrent to protect the public from being exposed to illegal pesticide residues. At the present time, FDA samples only a very small portion of all food grown, and therefore it needs to take strong action to deter the marketing of adulterated food. When FDA finds food contaminated with illegal pesticide residues, it is unable to prevent most of the food from reaching the public. Under the present system, the only adverse impact on growers or producers of adulterated food is the economic loss they suffer when such food is found and removed. The lack of civil penalties has created a perverse situation. Ironically, growers who voluntarily hold and remove food from the market suffer an economic loss while growers who do not remove adulterated food are usually able to market the food and avoid any economic loss. We believe that with civil penalty authority, FDA would be able to levy a monetary fine against those who ship food containing illegal residues and who did not remove the adulterated food. Such penalties should act as strong deterrents against future violations.

Matter for Consideration by the Congress

In view of the difficulties that FDA faces in trying to use existing authorities to prevent the marketing of domestic food containing illegal pesticide residues and the need to provide a strong deterrent against such shipments, the Congress may wish to give FDA legislative authority to assess civil penalties against growers of such food when it is not removed from the marketplace.

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